



DEPARTMENT OF DEFENSE

BILLING CODE 5001-06

Office of the Secretary

[Docket ID: DOD-2011-HA-0033]

Submission for OMB review; comment request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by [insert 30 days from publication of this notice in the Federal Register].

TITLE, FORM, AND OMB NUMBER: ACAM2000® Myopericarditis Registry; OMB Control Number 0720-TBD.

TYPE OF REQUEST: New

NUMBER OF RESPONDENTS: 20

RESPONSES PER RESPONDENT: 2

ANNUAL RESPONSES: 40

AVERAGE BURDEN PER RESPONSE: 30 minutes

ANNUAL BURDEN HOURS: 20 hours

NEEDS AND USES: The Food and Drug Administration required the establishment of several Phase IV post licensure studies to evaluate the long term safety of ACAM2000® smallpox vaccine. Among the required post licensure studies is the establishment of a myopericarditis registry. The ACAM2000® Myopericarditis Registry is designed to study the natural history of myopericarditis following receipt of the ACAM2000® vaccine, including evaluating factors that

may influence disease prognosis, thus addressing the FDA post-licensure requirement and ensuring the continued licensing of this vaccine.

AFFECTED PUBLIC: Individuals or households.

FREQUENCY: Semi-annually.

RESPONDENT'S OBLIGATION: Voluntary.

OMB DESK OFFICER: Ms. John Kraemer

Written comments and recommendations on the proposed information collection should be sent to Mr. Kraemer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD CLEARANCE OFFICER: Ms. Patricia Toppings

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Dated: December 23, 2011.

Aaron Siegel,
Alternate OSD Federal Register
Liaison Officer,
Department of Defense.

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